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Karen DeBenedictis
Warner-Lambert Company LLC
2800 Plymouth Road, 016/410E/PAT/6
Ann Arbor, MI 48105

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,001,876

AUG 15 2007

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,001,876, which claims a method of using the human drug product Lyrica® (pregabalin), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 533 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within <u>one month</u> of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 533 days.

The period of extension if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of September 29, 2006, (71 Fed. Reg. 57545) would be 1,135 days. Under 35 U.S.C. § 156(c):

$$
\begin{aligned}
\text{Period of Extension} \quad &= \quad \tfrac{1}{2}\,(\text{Testing Phase}) + \text{Approval Phase} \\
&= \quad \tfrac{1}{2}\,(2{,}852 - 1{,}435) + 427 \\
&= \quad 1{,}135 \text{ days (3.1 years)}
\end{aligned}
$$

Since the regulatory review period began January 10, 1996, before the patent issued (December 14, 1999), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From January 10, 1996, to and including December 14, 1999, is 1,435 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,135 days, would extend the patent from July 16, 2017 to August 24, 2020, which is beyond the 14-year limit (the approval date is December 14, 2004, thus the 14 year limit is December 14, 2018). The period of extension is thus limited to 533 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, July 16, 2017, to and including December 14, 2018, or 533 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.
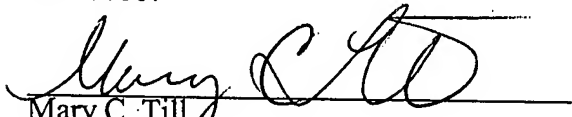
Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,001,876
Granted:	December 14, 1999
Original Expiration Date[1]:	July 16, 2017
Applicant:	Lakhbir Singh
Owner of Record:	Warner-Lambert Co.
Title:	ISOBUTYLGABA AND ITS DERIVATIVES FOR THE TREATMENT OF PAIN
Product Trade Name:	Lyrica® (pregabalin)
Term Extended:	533 days
Expiration Date of Extension:	December 30, 2018

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE   By FAX: (571) 273-7755
             Commissioner for Patents
             P.O. Box 1450
             Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
 for Patent Examination Policy

cc: Office of Regulatory Policy   RE: Lyrica® (pregabalin)
        HFD - 7   FDA Docket No.: 2006E-0005
        5600 Fishers Lane (Rockwall II Rm. 1101)
        Rockville, MD 20857

        Attention: Beverly Friedman

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[1]Subject to the provisions of 35 U.S.C. § 41(b).